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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/216,440	03/23/94	ZHOU	Y 418634ACCNC0

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12M1/0221

JORDAN, K  
EXAMINER

ART UNIT	PAPER NUMBER
1205	32

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED: 02/21/96

☐ This application has been examined    ☒ Responsive to communication filed on October 24, 1995    ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 months from the date of this letter.  
Failure to respond within the time period will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449              | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 27-29 and 31-32 are pending in the application.  
Of the above claims,        are withdrawn from consideration.
2. ☒ Claims 1-26 and 30 have been cancelled.
3. ☐ Claims        are allowed.
4. ☒ Claims 27-29 and 31-32 are rejected.
5. ☐ Claims        are objected to.
6. ☐ Claims        are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on       . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on        has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on        has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no.       ; filed on       .
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Claims 27-29 and 31-32 are pending in this application.

Claims 27-29 and 31-32 are rejected under 35 U.S.C. § 103 as being unpatentable over Deng (AQ) in view of Wang et al. (R) and Lin et al. (S) for reasons already of record.

The applicants' remarks have been considered but are unpersuasive. Applicants argue that the Chemical Abstracts reference by Lin et al. was incorrectly translated from the chinese publication in that the term "oral" used in the abstract was actually "intragastric gavage" in the full publication. It is further contended that the terms "oral" and "intragastric gavage" are not equivalent. It is conceded that oral administration is not the same as intragastric gavage (i.g.). However, it is the examiner's position that i.g. is highly suggestive of oral administration. While i.g. may be used on animals in testing situations such a use is suggestive of oral use not only in humans but animals as well. Administration by the i.g. route may be used by investigators because a known quantity may be administered without worrying about whether the animal will ingest the drug, how much it will ingest and if it will remain in stomach. Intragastric gavage is a common way used in animal research<sup>to</sup> simulate oral dosing but without the problems of accurate dosing described supra. When a drug is being investigated and animals are used to approximate the conditions under which a drug may be given to humans some accommodations

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must be made to account for the differences between humans and animals. The accommodation in this case of i.g. rather than oral administration is not unusual in animal experimentation when one is trying to give a standardized dose to minimize variability in the study. Thus, while the terms are not interchangeable per se, it is well known in the pharmaceutical art that i.g. may be used to simulate oral administration. Moreover, it should be noted that the claims are not limited to administration to humans. Finally, it should also be noted that the authors of the Lin et al. article appear to equate i.g. with oral administration as the opening paragraph of the translated publication states that the study was done to estimate the effects of oral artemether administration.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Jordan whose telephone number is (703) 308-4611. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JORDAN:jd  
FEBRUARY 14, 1996

  
KIMBERLY JORDAN  
PRIMARY EXAMINER  
GROUP 1200